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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,446	03/26/2001	Virginia C. Gordón	SAFTY-001BC	2044

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/21/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,446

Applicant(s)

GORDON ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 67-78 is/are pending in the application.
- 4a) Of the above claim(s) 68-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/03 has been entered.

2. Applicant's amendment filed 12/23/03 in Paper No. 10 is acknowledged and entered. Claims 1, 7, 67-69, 72, and 78 are amended by the amendment. *This amendment was entered as noted in the Advisory Action mailed on 1/16/03.*

3. Claims 1-7 and 67-78 are pending.

Election/Restrictions

4. Applicant has traversed the restriction requirement of the pending claims (Claims 1-7 and 67-78) They are group as followed:

a) Group I: Claims 1-7 and 67

b) Group II: Claims 68-77

c) Group III: Claim 78

The traversal is on the grounds that Group II and Group III should be rejoined with Group I, since the dependent claim 71 of Group II recite the element of Group I and the dependent claim 67 of Group I recite the element of Group III.

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This is not found persuasive because dependent claims are not relied upon as a criteria in the restriction requirement. Further, applicant has stated that the groups differ in scope. Therefore, these inventions are distinct for the reasons given in the previous Office Action mailed 8/22/02 and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. *This traversal was also address in the Advisory Action mailed on 1/16/03.*

The requirement is still deemed proper and is therefore made **FINAL**.

5. Claims 68-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 10.

6. This application contains claims 68-78 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

7. Claims 1-7 and 67 are treated on the merit in this Office Action.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

9. The previous rejection 35 USC 112, second paragraph, for claims 1-7 and 67 has been withdrawn in view of applicant's amendments of claims 1, 7, 67-69, 72, and 78.

Maintained Rejections

Claim Rejections - 35 USC § 112

10. Claims 1-7 and 67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended Claim 1 recites an apparatus that comprise of a housing, a filtrate-receiving vessel, a membrane, a sample-receiving well, a lid for sealing each of the filtrate receiving vessels and cavity of the housing and having a sample port bounded by an edge extending from the surface of the lid away from the cavity in which the edge is structure to retain the membrane, and a differential pressure source. Such a lid is not disclosed in the specification as originally filed.

The specification discloses four different apparatuses. The first apparatus comprise of a vacuum base, a test tube rack, a cover that is generally a flat member having a series of sample ports formed therein, membrane modules, and lids that are mountable in sealing contact on the rim of each primary membrane module and each lid has a limited air inflow port (pg. 13, lines 11-17; pg. 14, lines 1-2; pg. 16, lines 13-17; pg. 19, lines 8-12). The second apparatus comprise of a vacuum base, a filtrate receiving wells, plate-

type membrane modules having multiple cavities with bottom opening that have membranes mounted transversely within, and a cover having individual air inlet ports formed therein (pg. 18, lines 27-30 to pg. 19, lines 1-3). The third apparatus comprise of a vacuum base, a receiving unit with a plurality of receiving wells, a support member having a plurality of apertures, plate-type membrane modules having multiple cavities with bottom opening that have membranes mounted transversely within, a sample receiving unit with a plurality of sample receiving wells, and a lid that have a plurality of limited air inlet openings is placed in sealing contact on top of the sample receiving unit (pg. 21, lines 22-30 to pg. 22, lines 1-3). The forth apparatus comprise of a base, a receiving unit with a plurality of receiving wells, a support member having a plurality of apertures, first and second membrane modules and a positive pressure lid (pg. 24, lines 16-19).

Nowhere in the specification is there a teaching of the device as claimed in Claim 1. The apparatuses disclosed in the specification require that the lid either be in sealing contact with the sample receiving unit or the membrane module. The specification does not teach a lid, i.e. one, for sealing each of the filtrate receiving vessels and the cavity of the housing.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

Response to Arguments

11. It is noted that applicant has included the withdrawn claims 68-78 in their arguments of the following rejections eventhough claims 68-78 are not examined.

12. Applicant's argument directed to the above rejection 35 U.S.C. 112, first paragraph, for claims 1-7 and 67 was considered but they are not persuasive for the following reasons.

Applicant alleges that "[T]he "lid" in claim 1 was intended to refer to cover 12 of the test apparatus shown in fig. 5-9 of the present application and described in page 13, line 10 through page 18, line 25 of the specification. Sealing lids 24 may actually be considered to be part of the cover. Thus, when the lids 24 are in place, the cover 12 does indeed seal each individual filtrate receiving vessel 15 as well as the cavity 17 of the housing 16" (pg. 10 of response).

Applicant's arguments are not convincing since the cover (ref #12) does not seal "...each of said filtrate receiving vessels and said cavity of said housing". The cover (ref #12) has a series of sample port (ref #13) that directly align with the mouth of the filtrate receiving vessel (ref #15) when the cover and the test tube rack (ref #14) are properly mounted within the apparatus (ref #10) (see fig. 5-6; pg. 14, lines 1-4). Therefore, the cover (ref #12) does not seal each of the filtrate receiving vessel (ref #15) because to seal is to close something firmly or make something watertight or airtight so the sample port in the cover does not prevent closure or make the filtrate receiving vessel (ref #15) watertight. Furthermore, sealing lids (ref. #24) (should be ref. #22 since ref. #24 is the air inflow port (see pg. 16, lines 13-15 of amendment filed 4/29/02)) are mountable in sealing contact on the rim (ref. #20) of each primary membrane module (ref. #20) not the filtrate receiving vessel (ref #15). From fig. 5-6, the sealing lids (ref. #22) would seal the sample receiving vessel (ref. #21) and not the filtrate receiving vessel (ref #15) even if

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the sealing lids are considered to be part of the cover. Therefore, the rejection under 35 USC 112, first paragraph, is maintained. *This traversal was also address in the Advisory Action mailed on 1/16/03.*

Claim Rejections - 35 USC § 102

13. Claims 1-2, 4-7 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (US Patent 4,902,481).

Clark teaches a multiwell filtration apparatus for the assay of biological and biochemical materials (col. 1, lines 66-68; fig. 1). The multiwell filtration apparatus comprise of a base (housing having a cavity) (ref. #2 of fig. 1), a receiving plate (ref. #8 of fig. 1) having a plurality of individual chambers (ref. #9 of fig. 1) for collecting filtrate, a plate (ref. #13 of fig. 1-3) that house the membrane (ref. #30 of fig. 1) and positioned over each individual chamber of ref. #9 (col. 3, lines 5-25), a support (lid) (ref. #10 of fig. 1) that covers the receiving plate (ref. #8) and the base, and a filtration plate (ref. #12 of fig. 1) with individual well (ref. #11 of fig. 1), which has an opening (fig. 1 and 3) (col. 2, lines 53-68 to col. 3, lines 1-25; fig. 1-3). The base acts a vacuum chamber (col. 2, lines 56-59). The membrane can be bonded to the filtration plate (ref. #12) (col. 3, lines 26-28) that would form two portion of the membrane. The plate (ref. #13) is snap or press to fit filtration plate (ref #12) (col. 3, lines 17-18; fig. 3). The multiwell filtration apparatus of Clark anticipates the claimed apparatus.

Response to Arguments

14. It is noted that applicant has included the withdrawn claims 68-78 in their arguments of the following rejections eventhough claims 68-78 are not examined.

15. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by as being unpatentable over Clark et al. (US Patent 4,902,481) for claims 1-2, 4-7 and 67 were considered but they are not persuasive for the following reasons.

Applicant contends that Clark et al. do not anticipate the claimed invention because Clark et al. do not disclose each and every feature of the claimed invention. That is Clark et al. do not have a sample port that is part of the "cover" or support and that the membrane modules have portions made of a hard material and portions made of an elestomer material, wherein the elastomeric portions abut against neighboring components of the apparatus.

Applicant's arguments are not convincing since Clark et al. do anticipate the claimed invention because the sample ports (ref #11) are part of the plate (ref #12) (see fig. 1 and 3) and the filtration membrane (ref. #30) can be bonded to plate (ref #12) or can be held in position by being compressed between plate (ref #12) and plate (ref #113) (see fig. 3; col. 3, lines 26-28). In fig. 3 of Clark et al., the elastomeric portion (ref. #30) does abut the neighboring portion (ref. #24) and the membrane module (ref #12) does comprise an elastomer portion (ref. #30) and hard material portion (ref. #40). Therefore, Clark et al. do anticipate the claimed invention. *This traversal was also address in the Advisory Action mailed on 1/16/03.*

Claim Rejections - 35 USC § 103

16. Claims 1-7 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Patent 4,902,481) and Oprandy (US Patent 5,039,493). ***(Note: This rejection is exactly the same as disclosed in the Final Office Action, however the format is modified for clarification.)***

Clark teaches a multiwell filtration apparatus for the assay of biological and biochemical materials (col. 1, lines 66-68; fig. 1). The multiwell filtration apparatus comprise of a base (housing having a cavity) (ref. #2 of fig. 1), a receiving plate (ref. #8 of fig. 1) having a plurality of individual chambers (ref. #9 of fig. 1) for collecting filtrate, a plate (ref. #13 of fig. 1-3) that house the membrane (ref. #30 of fig. 1) and positioned over each individual chamber of ref. #9 (col. 3, lines 5-25), a support (lid) (ref. #10 of fig. 1) that covers the receiving plate (ref. #8) and the base, and a filtration plate (ref. #12 of fig. 1) with individual well (ref. #11 of fig. 1), which has an opening (fig. 1 and 3) (col. 2, lines 53-68 to col. 3, lines 1-25; fig. 1-3). The base acts a vacuum chamber (col. 2, lines 56-59). The membrane can be bonded to the filtration plate (ref. #12) (col. 3, lines 26-28) that would form two portion of the membrane. The plate (ref. #13) is snap or press to fit filtration plate (ref #12) (col. 3, lines 17-18; fig. 3).

The apparatus of Clark differs from the claimed invention in failing to specifically teach a pressure source that provides a positive pressure.

Oprandy disclosed a positive pressure blotting apparatus with filtering means (col. 1, lines 65-68 to col. 2, lines 1-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the vacuum of Clark with a pressure source that provides a positive

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pressure as taught by Oprandy because positive and negative pressure sources are functionally equivalent means for achieving filtration of a sample. Specifically, Oprandy teaches that imposing a positive pressure on a filtration system provides the advantage of directly concentrating and forcing the sample through the membrane, achieving greater efficiency for the same power output as compare to a device such as a vacuum (col. 3, lines 15-21).

Response to Arguments

17. It is noted that applicant has included the withdrawn claims 68-78 in their arguments of the following rejections even though claims 68-78 are not examined.

18. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Clark et al. (US Patent 4,902,481) and Oprandy (US Patent 5,039,493) for claims 1-7 and 67 were considered but they are not persuasive for the following reasons.

Applicant argues that because Clark et al. does not disclosed each and every feature of the claimed invention and would not be made obvious by Clark et al. in view of Oprandy.

Applicant's arguments are not convincing since Clark et al. does disclose each and every feature of the claimed invention as discussed above. Therefore, Clark et al. and Oprandy are made obvious over the presently claimed invention. *This traversal was also address in the Advisory Action mailed on 1/16/03.*

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
July 9, 2003


ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600